Remarks

Claims 42 and 43 have been added. Claims 1 - 43 remain in the application. Claims 1 - 38 and 41 have been withdrawn from consideration by the Examiner. Reconsideration of this application and the amendments is requested.

The specification has been amended to up-date the status of the parent case which is now a U. S. patent and to correct grammar. Claim 1 has been amended as suggested by the Examiner.

Rejections under 35 USC 112, first paragraph

Claims 39 and 40 stand rejected under the first paragraph of the statute as failing to enable one of ordinary skill in the art to make or use the article without undue experimentation. The Examiner refers to the case law as exemplifying factors she considered in arriving at her position.

In re Wands, 8 USPQ2d 1400, is cited by the Examiner as describing the factors to be considered in determining enablement. It should be noted that the Court condoned an acceptable amount of experimentation to reproduce the inventor's results. There is a detailed discussion in that case with regard to the term, "undue experimentation," with the conclusion that the emphasis must be placed on, "undue," and not experimentation. The Court stated, "Enablement is not precluded by the necessity

> for some experimentation such as routine screening. However, experimentation needed to practice the invention must not be undue

> experimentation. The key word is 'undue,' not 'experimentation'."

If the screening follows conventional or established procedures to establish the presence of a known or desired attribute, regardless of the length of the screening or the number of tests, or the number of steps in a test, it is not undue.

The Court went on to say, "Wands disclosure provides considerable

> direction and guidance on how to practice their invention and presents working examples. There was a high level of skill in the art at the time when the application was filed, and all the methods needed to practice the invention were well known."

After reviewing these factors, the Court overturned the decision of the Board of Appeals (which used these same factors), at least partly, because the procedure for developing monoclonal antibodies was generally known when the application was filed and because the Court concluded that, " Practitioners in the art are

> prepared to screen negative hydridomas in order to find one that makes the desired antibody. * * * *. However, it seems unlikely that undue experimentation would be defined in terms of the number of hydridomas that were never screened."

The subject matter of this case does not involve genetic engineering or development of monoclonal antibodies. However, the art of transdermal medication was fairly well known when the parent application, now a U. S. patent, was filed, as exemplified by the

prior art cited in the patent and here . In the instant application, there is, indeed, experimentation. The experimentation is in the nature of screening certain compounds and solutions to determine certain inherent properties. Such screenings are standard, known routines in the fields of quantitative chemistry, qualitative chemistry and physical chemistry. There is no, "undue," experimentation in conducting these tests. Dipole moments and van der Waal's forces may be determined for most chemicals by reference to tables in standard texts or published chemical software or by well known lab procedures.

The instant specification has 18 specific examples of the invention and it contains direction and guidance for producing or reproducing the method and product. See pages 31 - 86 explaining the physical chemistry calculations necessary to screen the properties of the constituents of an effective TDS . This exhaustive dissertation on the factors necessary for an effective transdermal medication, including the calculations required to achieve such medications, is the antithesis of a lack of enablement.

Referring to the factors included in the rejection, (1) the nature of the invention is explained by the Examiner however, the several references, in the disclosure, to standard texts and/or published software as the source of the information concerning molecular properties has been ignored. Further, there are specific examples of formulations in the disclosure. As for how to calculate mole amounts and multiply by dipole moments, such calculations are used in undergraduate chemistry. The Examiner recognizes that the skill level is "high" in factor (4) and, of course, the disclosure is directed to one of ordinary skill in the art.

In the discussion of Factor (2), the Examiner comments that the claims encompass

wide varieties of compounds and are therefore broad. However, the claims are directed to a specific method of determining which chemicals to combine to form an effective transdermal medication. The number of possible compounds is not important but the steps in the method to reach the final product. These steps are discussed in the specification with examples.

In factor number (3), the Examiner mentions that the state of the art recognizes transdermal medication and that the prior art does not recognize quantifying molecular properties and comparing them to arrive at a compound. This is true and is why the parent application has matured into U. S. Patent No. 6,444,234 and this divisional was filed.

Factor (4) concerns the level of the art, mentioned above, and is directed to at least the level of unsupervised research chemists and pharmacologists.

The statements made under factor (5) are refuted by the 18 specific examples and pp. 31 - 86 of the specification explaining the products and method.

With regard to (factor 6), a step in all the methods includes picking an active agent and determining an effective dose. This is found in any Pharmacopoeia or desk reference or other published materials by drug companies. Also found in such references is the solubility of an active agent. There is no attempt in this application to relate different classes of active ingredients to each other or to related classes of solvents. As in the Wands case, cited above, there may be a negative here when the molecular properties of an active agent, a solvent and other ingredients do not fall within the parameters of the method steps. But the Court said that finding negatives is not Undue experimentation.

With regard to factor 7, there are 18 examples in this specification. Again, routine chemistry screening or testing is used to quantify and comparison is self explanatory.

Contrary to the Examiner's statement is factor 8, the whole point of this invention is to take the trial and error method out of combining active agents and solvents for transdermal administration. This invention is an improvement over the trial and eror method. This invention is not about specific compounds but about a system for efficiently, projecting, determining and selecting the most probable combinations of compounds to produce an effective transdermal medication.

The claims have been amended to clarify the method steps in relation to the disclosed method of arriving at an effective transdermal compound.

Rejections under 35 USC 112, second paragraph

Claims 39 - 40 stand rejected as incomplete in the omission of a required step in the method of making the TDS. As set out by the independent claim 39, the method steps start with the selection of an active ingredient or medicament. Once the active ingredient has been selected, the remaining steps of the method and the quantitative parameters of the other constituents are established. The method includes steps of calculating the molecular forces to arrive at a delivery system constituting a proper carrier for an effective dose of the active agent. The carrier efficaciously penetrates the skin of a patient to deliver the effective dose to the patient.

The, "combining," step(h), of the method claim brings together the constituents of the other steps and produces the TDS. Dependent claim 40, 42 and 43 also have a,

"combining," step to produce a complete product.

Contrary to the Examiner's conclusion, the instant invention is the removal of the, "undue experimentation," from trying to find certain combinations of active agents, solvents and solutes that will perform transdermal penetration to deliver an effective dose of an active agent in an acceptable time frame. The experimentation, in the instant case, may be the adding and subtracting of the numbers generated by the lab tests, tables or software. Until disclosed by the inventors, the prior art did not recognize that these values associated with physical chemistry characteristics or properties of the constituent compounds dissolved in solutions could be summed to arrive at values for the whole solution - values or properties that predict how stable the solution will be and, in the process, dramatically reduce experimentation necessary to arrive at a practicable solution. Further, until disclosed by the inventors, the prior art did not recognize that effective transdermal medications had these claimed particular properties and by systematically tracking and combining these certain properties of prospective constituents, with a view to their effect on the systems's mole moment, an effective transdermal medication could be predicted and produced without being the result of trial and error testing.

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